

# **EXHIBIT 1**

# **Joseph Carbone**

## **Reliance List**

***in Addition to Materials Referenced in Report***

**MDL Wave 1**

Medical Literature

Abdelmonem, A. – Vaginal length and incidence of dyspareunia after total abdominal versus vaginal hysterectomy (2010)
Abdelwahab 2010 - Tension-free vaginal tape versus secure tension-free vaginal tape in treatment of female stress urinary incontinence. Curr Urol 2010; 4:93-98.
Abduljabbar 2012 - Comparison of the classic TTV and TTV-Secur. Prime Journal, Vol 2(9), 344-347, October 31 <sup>st</sup> , 2012.
Abed, H., et al. – Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review (2011)
Alperin, M., et al. – Perioperative outcomes of the Prolift pelvic floor repair systems following introduction to a urogynecology teaching service (2008)
Altman, D., et al. – Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse (May 12, 2011)
Altman, D., et al. – Perioperative Morbidity Using Transvaginal Mesh in Pelvic Organ Prolapse Repair (2007)
Altman, D., et al. – Sexual Dysfunction After Trocar-Guided Transvaginal Mesh Repair of Pelvic Organ Prolapse (January 2009)
Altman, D., et al. – Short-term outcome after transvaginal mesh repair of pelvic organ prolapse (2007)
Amid, P. – Classification of biomaterials and their related complications in abdominal wall hernia surgery (1997)
Anderson, K., et al. – Surgical Management of ICS/IUGA Class 1-4 Transvaginal Mesh (TVM) Prolapse Kit Complications: 8-year Review of 82 Patients from a Single Center (5/19/2015)
Balchandra, P., et al. – Perioperative outcomes and prospective patient reported outcome measures for transvaginal mesh surgery (2/9/2015)
Barber 2012 - Single-incision mini-sling compared with tension-free vaginal tape for the treatment of stress urinary incontinence. Obstetrics & Gynecology, Vol. 119, No. 2, Part 1, February 2012.
Barber, M., et al. – Comparison of 2 Transvaginal Surgical Approaches and Perioperative Behavioral Therapy for Apical Vaginal Prolapse The OPTIMAL Randomized Trial (2014)
Bartley, J., et al. – Secondary surgery after vaginal prolapse repair with mesh is more common for stress incontinence and voiding dysfunction than for mesh problems or prolapse recurrence (2015)
Benbouzid, S., et al. – Pelvic organ prolapse transvaginal repair by the Prolift system: Evaluation of efficacy and complications after a 4.5 years follow up (2012)
Benson, J., et al. – Vaginal versus abdominal reconstructive surgery for the treatment of pelvic support defects: A prospective randomized study with long-term outcome evaluation (1996)
Bernard, D., et al. – Pelvic Organ Prolapse Treatment by the Vaginal Route using a Vypro Composite Mesh: Preliminary Results about 106 Cases
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Berrocal, J., et al. – Conceptual advances in the surgical management of genital prolapse (November 2004)
Bianchi-Ferraro 2012 - Single-incision sling compared with transobturator sling for treating stress urinary incontinence - a randomized controlled trial (TTV-O, TTV-S). Int Urogynecol J (2012)
Bianchi-Ferraro 2014 - Randomized controlled trial comparing TTV-O and TTV-S for the treatment of stress urinary incontinence. 2-year results. Int Urogynecol J (2014) 25: 1343-1348.

Medical Literature

Brubaker, B., et al. – Factorial comparison of 2 Transvaginal Surgical Approaches and of Perioperative Behavioral Therapy for Women with Apical Vaginal Prolapse The OPTIMAL Randomized Trial (Supplementary Online Content) (2014)
Caquant, C., et al. – Prolift Mesh (Gynecare) for Pelvic Organ Prolapse Surgical Treatment using the TVM Group Technique: A Retrospective Study of 687 Patients
Caquant, F., et al. – Safety of Trans Vaginal Mesh procedure: Retrospective study of 684 patients (2008)
Coady D. Chronic sexual pain. A layered guide to evaluation. Contemporary Ob/Gyn, September 2015, pp. 18-28.
Da Silveira, S., et al. – Multicenter, randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment (September 2014)
Damoiseaux, A., et al. – Long-term Follow-up (7 years) of a randomized controlled trial: trocar-guided mesh compared with conventional vaginal repair in recurrent pelvic organ prolapse (40th Annual Meeting, June 9-13, 2015)
Dandolu, V., et al. – Mesh Complications in US after Transvaginal Mesh Repair Versus Abdominal or Laparoscopic Sacrocolpopexy
De Landsheere, L., et al. – Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years' median follow-up (2012)
Dietz, V., et al. – Pelvic organ prolapse and sexual function (2013)
Diwadkar, G., et al. – Complication and Reoperation Rates After Apical Vaginal Prolapse Surgical Repair (February 2009)
Elmer, C., et al. – Risk Factors for Mesh Complications after Trocar Guided Transvaginal Mesh Kit Repair of Anterior Vaginal Wall Prolapse (2012)
Fatton, B., et al. – Transvaginal repair of genital prolapse: preliminary results of a new tension-free vaginal mesh (Prolift technique) – a case series multicentric study (2006)
Feiner, M., et al. – The Cochrane Collaboration – Surgical management of pelvis organ prolapse in women (Review) (2013)
Fialkow, M., et al. – Incidence of recurrent pelvic organ prolapse 10 years following primary surgical management: a retrospective cohort study (November 2007)
Firoozi, F., et al. – Short and Intermediate-Term Complications of the Prolift Transvaginal Mesh Procedure (2009)
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Gupta, P., et al. – The Impact of Comorbid Chronic Pain Syndromes on Sexual Activity and Dyspareunia after Pelvic Organ Prolapse Repair (5/16/2015)
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Heinonen, P., et al. – Long-Term Outcome after Transvaginal Mesh Repair of Pelvic Organ Prolapse
Higgs, M., et al. – Vaginal repair with mesh versus colporrhaphy for prolapse: a randomized controlled trial (2009)

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Jacquetin, B. et al. – Complications of vaginal mesh: our experience (2009)
Jacquetin, B., et al. – Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 5-year prospective follow-up study (2013)
Kahn, M., et al. – Posterior colporrhaphy: its effects on bowel and sexual function (January 1997)
Karram 2007 - An Evaluation Of The Gynecare TVT Secur System (Tension-Free Support For Incontinence) For The Treatment Of Stress Urinary Incontinence. Int Urogynecol J (2007) 18 Suppl 1)S1-S24.
Karram, M., et al. – Surgery for posterior vaginal wall prolapse (2013)
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Khandwala 2012 - TVT-Secur in Office Sling Procedure Under Local Anesthesia: A Prospective 2-Year Analysis. Female Pelvic Medicine & Reconstructive Surgery, Volume 18, Number 4, July/August 2012.
King A. Is there an association between polypropylene midurethral slings and malignancy. Urology 84: 789-792, 2014
Komesu, Y., et al. – Posterior repair and sexual function (July 2007)
Kozal, S., et al. – Morbidity and functional mid-term outcomes using Prolift pelvic floor repair systems (2014)
Landsheere, L., et al. – Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years' median follow-up (2012)
Lane, F. – Repair of Posthysterectomy Vaginal-Vault Prolapse (August 9, 1961)
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Long, C., et al. Three-year outcome of transvaginal mesh repair for the treatment of pelvic organ prolapse (2011)
Lowman, J., et al. – Does the Prolift system cause dyspareunia? (December 2008)
Lucente, V., et al. – Pelvic Organ Prolapse
Luck, A., et al. – Suture erosion and wound dehiscence with permanent versus absorbable suture in reconstructive posterior vaginal surgery (2005)
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Maher C, et al. (full 141pp) Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse (Review). The Cochrane Collaboration (2016)
Maher C, et al. (Summary) Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse (Review). The Cochrane Collaboration (2016)
Mattimore, J., et al. – The History of Pelvic Organ Prolapse from Antiquity to Present Day (5/17/2015)

Migliari, R., et al. – Tension-Free Vaginal Mesh Repair for Anterior Vaginal Wall Prolapse (2000)
Miller, D., et al. – Prospective Clinical Assessment of the Transvaginal Mesh Technique for Treatment of Pelvic Organ Prolapse – 5-Year Results (2011)
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Neuman 2007 - TVT-SECUR: 100 teaching operations with a novel anti-incontinence procedure. Pelviperineology 2007; 26:121-123.
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Nicita, G. – A New Operation for Genitourinary Prolapse (4/17/1998)
Nygaard, I., et al. – Long-term Outcomes Following Abdominal Sacrocolpopexy for Pelvic Organ Prolapse (2013)
Nygaard, I., et al. – Prevalence of Symptomatic Pelvic Floor Disorders in US Women (2008)
Pandit, L., et al. – Postmenopausal Vaginal Atrophy and Atrophic Vaginitis (October 1997)
Pardo 2010 - Effectiveness of TVT-Secur compared with Miniarc for stress urinary incontinence. A randomized controlled trial with mini-sling. Int Urogynecol J (2010) 21 (Suppl 1): S1-S428.
Sand, P., et al. – Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles (2001)
Sato, K., et al. – Sexual function in female patients who underwent pelvic floor reconstruction with follow-up for a minimum of 5 years (5/19/2015)
Seo 2011 - Comparison between transobturator vaginal tape inside out and single incision sling system in the treatment of female stress urinary incontinence: Prospective randomized study.
Silva, W., et al. – Uterosacral Ligament Vault Suspension (August 2006)
Sokol, A., et al. – One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse (January 2012)
Sola 2009 - Third Generation Sub-Mid Urethral Mesh: Experience With 110 TVT-Secur. Arch Esp Urol 2009; 62(5): 376-388.
Sung, V., et al. – Changes in Bowel Symptoms 1 Year after Rectocele Repair (2012)
Svabik, K., et al. – Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial (December 2013)
Tang 2014 - Outcome and sexual function after transobturator tape procedure versus tension-free vaginal tape Secur: a randomized controlled trial. Menopause, Vol. 21, No. 6 (2014).
Tartaglia 2009 - Third-Generation Tension-Free Tape for Female Stress Urinary Incontinence. The Journal of Urology, Vol. 182, 612-615, August 2009.
Tincello 2011 - The TVT Worldwide Observational Registry for Long-Term Data. Safety and Efficacy of Suburethral Sling Insertion Approaches for Stress Urinary Incontinence in Women. The Journal of Urology, Vol. 186, 2310-2315, December 2011.
Toglia, M., - Suture erosion rates and long-term surgical outcomes in patients undergoing sacrospinous ligament suspension with braided polyester suture (May 2008)
Tommaselli 2010 - Efficacy and safety of TTVT-O and TVT-Secur in the treatment of female stress urinary incontinence: 1-year follow-up. Int Urogynecol J (2010) 21:1211-1217
Tommaselli 2012 - TVT-Secur for the treatment of female stress urinary incontinence: a 24-month follow-up retrospective study. Arch Gynecol Obstet (2012) 286:415-421.

Tommaselli 2013 - Tension-Free Vaginal Tape-O and -Secur for the Treatment of Stress Urinary Incontinence. A Thirty-Six-Month follow-up Single-blind Double-arm, Randomized study. Journal of Minimally Invasive Gynecology, Vol 20, No 2, March/April 2013.
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Ubertazzi, E.P., et al. Trans Vaginal Mesh (TVM) Five Years Follow Up: A Retrospective Study from Latam (2015)
Walsh 2011 TTV-Secur mini-sling for stress urinary incontinence - a review of outcomes at 12 months. BJUI (2011) 108, 652-657
Wang 2011 Comparison of three mid-urethral tension-free tapes (TVT, TVT-O, and TTV-Secur) in the treatment of female stress urinary incontinence: 1-year follow-up. Int Urogynecol J (2011) 22:1369-1374.
Weber, A., et al. Anterior colporrhaphy: A randomized trial of three surgical techniques (2001)
Weber, A., et al. Sexual function and vaginal anatomy in women before and after surgery for pelvic organ prolapse and urinary incontinence (2000)
Whiteside, J., et al. Risk factors for prolapse recurrence after vaginal repair (June 2004)
Withagen, M., et al. Sexual Functioning after Tension Free Vaginal Mesh Procedure (Prolift) for Pelvic Organ Prolapse
Withagen, M., et al. Trocar-Guided Mesh Compared With Conventional Vaginal Repair in Recurrent Prolapse (February 2011)
Woods 2008 Vaginal Sling for Stress Urinary Incontinence Under Local Anesthetic in the Office Setting. Journal of Pelvic Medicine & Surgery, Volume 14, Number 4, July/August 2008.
Wu, C., et al. Concomitant trocar-guided transvaginal mesh surgery with a midurethral sling in treating advanced pelvic organ prolapse associated with stress or occult stress urinary incontinence (2012)
Wu, J., et al. Lifetime Risk of Stress Urinary Incontinence or Pelvic Organ Prolapse Surgery (June 2014)
Yazdany, T., et al. Suture complications in a teaching institute among patients undergoing uterosacral ligament suspension with permanent braided suture (2010)

<b>Document Description [Bates Range]</b>
Ethicon Expert Meeting – Meshes for Pelvic Floor Repair (Friday, February 23, 2007)
Ethicon Expert Meeting – Meshes for Pelvic Floor Repair (Friday, June 2, 2006)
Gynecare Gynemesh* PS (2003)
Gynecare Prolift – ETH-10977 (2009)
Gynecare Prolift – Power Point Presentation (2005)
Gynecare Prolift – Power Point Presentation (2007)
Gynecare Prolift – Surgeon's Resource Monograph (2007)
Gynecare Prolift – Surgical Technique
Gynecare Prolift Brochure (2004)
Pelvic Organ Prolapse – Patient Counseling Guide (2011)
Treatment for Pelvic Organ Prolapse – Stop Coping. Start Living brochure (2008)
2006 Apr 19 - Laser Cut Mesh for Gynecare TVT- CER Laser Cut Mesh [ETH.MESH.00167104 -10]
2006 Mar 3 Flatow memo - CPC-2006-0165 Performance evaluation of TVT PROLENE blue Mesh_ Elongation Properties of Mechanical Cut verses Laser Cut
ETH.MESH.02248778 - Mechanical vs Machine Cut (Laser.Ultrasonic) Mesh Particle loss less than 2 percent for

Other Materials

**Publically Available**

AUA Position Statement on the Use of Vaginal Mesh for the Repair of Pelvic Organ Prolapse (7/30/2014)
Committee on Gynecologic Practice Opinion: Vaginal Placement of Synthetic Mesh for Pelvic Organ Prolapse (December 2011)
FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence (2014)
FDA Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication (7/13/2011)
IUGA – Pelvic Organ Prolapse – A Guide for Women
Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders (March 26, 2013)
The American College of Obstetricians and Gynecologists – FAQ Gynecologic Problems (May 2011)
The American College of Obstetricians and Gynecologists – FAQ Surgery for Pelvic Organ Prolapse (December 2013)
2014 Mar 12 - AUGS SUFU Provider FAQs MUS for SUI

**Other**

List of Doctors Paper

Pelvic Organ Prolapse – Get the Facts, Be Informed, Make YOUR Best Decision (Brochure) (2005)

<b>Expert Reports</b>
Blaivas, Jerry (Prolift General)
Blaivas, Jerry (TVT Abbrev General)
Blaivas, Jerry (TVT Exact General)
Blaivas, Jerry (TVT -R General)
Blaivas, Jerry (TVT-O General)
Blaivas, Jerry (TVT-S General)
Elliott, Daniel (Prolift General)
Elliott, Daniel (TVT General)
Elliott, Daniel (TVT-O General)
Elliott, Daniel (TVT-S General)
Margolis (TVT General)
Rosenzweig, Bruce (Prosima General)
Rosenzweig, Bruce (TVT & TVT-O General)
Rosenzweig, Bruce (TVT Abbrev General)
Rosenzweig, Bruce (TVT Exact General)
Rosenzweig, Bruce (TVT-S General Causation Report)
Rosenzweig, Bruce (TVT-S General)